TCI™ Group
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DEC 0 5 2001

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K013323**.

Submitter Information (21 CFR 807.92(a)(1))

Submitter: TCI New York
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Contact: Mr. Gerry Rausnitz
President and CEO
TCI New York

Summary Date: October 4, 2001

Name of Device and Classification (21 CFR 807.92(a)(2))

Name (trade): TCI Ovulation Tester™ (Ovulation Tester)

Name (usual): luteinizing hormone test system

Classification: 21 CFR 862.1485, Class 1, CEP (75)

Identification of Legally Marketed Predicate Device(s) (21 CFR 807.92 (a)(3))

The Ovulation Tester is substantially equivalent to Conceive® Ovulation Predictor (Quidel Corporation, San Diego, CA), cleared under premarket notification K953063.

The Ovulation Tester is identical or similar to its predicate in terms of: intended use, risk to patient, result interpretation (positive or negative for impending ovulation), test availability (OTC), and clinical performance (ability to identify impending ovulation).

Description of Device (21 CFR 807.92 (a)(4))

The Ovulation Tester is a complete system for identifying the most fertile day(s) of a woman's menstrual cycle using a direct saliva sample. These fertile days are detected through the observation of distinctive crystallization or ferning patterns seen on a glass slide. The test is self-administered and is completely portable. The system requires no reagents nor specific storage conditions, can be performed with relative ease, and results may be interpreted within approximately 10 minutes of saliva application. The test is intended for over-the-counter (OTC) use.

The Ovulation Tester Kit consists of:

1. the Ovulation Tester device (see below for further details) with tracking disk
2. an extra tracking disk
3. the saliva brush applicator
4. the Instruction Booklet
5. a marking pencil
6. the storage bag

The Ovulation Tester device consists of

1. the black microscope eyepiece
2. the rubber eye cup (shown installed over the black eyepiece)
3. the tracking disk (stored in the unit)
4. the battery (already in place)
5. the light source (already in place)

The Ovulation Tester is a hand-held, circular shaped "minimicroscope" containing four sets of five miniaturized microscope slides in a plastic case. The slides are made from optical glass, and are placed on a round tracking disk; the disk serves as the platform for viewing the dried saliva patterns. One tracking disk may be used for several months. The device also includes a small built-in light (light emitting diode [LED]) as its light source for viewing the slides, a replaceable battery (1.5 volt) and electronic circuitry.

The system is designed to perform sequential testing over five consecutive days; the testing days are based on the woman's expected cycle length. To perform the test, a woman places a thin coat of saliva on a slide by means of the saliva brush applicator. After the saliva has been allowed to air-dry, the tracking disk is rotated so that the day-specific slide lines up at the proper opening. The device is brought in close proximity to the viewing eye, and a black button on the back of the device is pushed; this activates the green light to allow viewing of the dried saliva patterns. The preovulatory days are characterized by ferning patterns, while, on other days, the slides will appear with "debris-like" substances such as dots, circles, or cells.

Intended Use (21 CFR 807.92 (a)(5))

The Ovulation Tester is an over-the-counter device intended to detect the most fertile days of a woman's menstrual cycle by the direct visualization of the characteristic peri-ovulatory ferning pattern seen in dried saliva. This ferning occurs due to increased levels of estrogen.

Similarities to the Predicate(s) (21 CFR 807.92 (a)(6))

A summary table of the similarities and differences between the Ovulation Tester and the predicate device (Conceive) follows.

Comparison Table of Characteristics:
TCI-31 Lifelong Ovulation Tester™ and Conceive®

Indications for use	Identify the periovulatory phase of the menstrual cycle to help a woman become pregnant	Identify the periovulatory phase of the menstrual cycle to help a woman become pregnant
Risk to Patient	None; test is non-invasive. Results (positive or negative) do not lead to critical decisions or outcomes	None; test is non-invasive. Results (positive or negative) do not lead to critical decisions or outcomes
Result Interpretation	Qualitative; positive or negative for impending ovulation	Qualitative; positive or negative for impending ovulation
Test Availability	Over-the-counter (OTC)	Over-the-counter (OTC)
Sample matrix	Saliva	Urine
Measured Effect or Analyte	Ferning under the influence of estrogen (a hormone)	Urinary LH (a hormone)
Result Stability	Dried saliva pattern is stable indefinitely (several months)	LH stick must be interpreted within 5 minutes of adding the urine sample

Brief Discussion of Nonclinical and Clinical Data (21 CFR 807.92(b)(1,2))

In clinical studies with 166 premenopausal women aged 18 to 40, the Ovulation Tester was 93% accurate in identifying the impending ovulation as compared to a urinary LH kit. Salivary fern ing was identified within 48 hours pre or post the first day of the LH surge in 155/166 cycles.

In consumer studies with 163 untrained women, the readability of the Ovulation Tester was 93%. The consumers were able to identify salivary fern ing on at least one of the days when a trained reader identified fern ing in 152/163 cycles. In another evaluation, it was found that consumers could identify their fern ing during the five days around ovulation 92% of the time.

Performance Data - Conclusions (21 CFR 807.92 (b)(3))

The Ovulation Tester is substantially equivalent to the Conceive® Ovulation Predictor. Both methods identify the most fertile days of a woman's menstrual cycle and impending ovulation. Conceive is a urinary LH kit that identifies the midcycle LH surge, and the Ovulation Tester detects the characteristic pre-ovulatory fern ing pattern seen in dried saliva. This fern ing occurs due to increased levels of pre-ovulatory estrogen.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 0 5 2001

TCI New York
c/o Ms. Erika B. Ammirati
Ammirati Regulatory Consulting
575 Shirlynn Court
Los Altos, CA 94022

Re: k013323
Trade/Device Name: TCI Ovulation Tester™
Regulation Number: 21 CFR 862.1485
Regulation Name: Luteinizing hormone test system
Regulatory Class: Class I
Product Code: CEP
Dated: October 4, 2001
Received: October 5, 2001

Dear Ms. Ammirati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(K) Number (if known): K013323

Device Name: TCI Ovulation Tester™

Indications for Use:

The Ovulation Tester is an over-the-counter device intended to detect the most fertile days of a woman's menstrual cycle by the direct visualization of the characteristic peri-ovulatory ferning pattern seen in dried saliva. This ferning occurs due to increased levels of estrogen.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 1013323

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE AS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___ OR Over –the-Counter Use ✓
(Per 21 CFR 801.109)